

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 22, 2024

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WILLA K. LAU,	*	PUBLISHED
	*	
Petitioner,	*	No. 19-1956V
	*	
v.	*	Special Master Dorsey
	*	
SECRETARY OF HEALTH	*	Entitlement; Influenza (“Flu”) Vaccine;
AND HUMAN SERVICES,	*	Guillain-Barré Syndrome (“GBS”);
	*	Facial Paralysis.
Respondent.	*	
	*	
* * * * *	*	

Richard H. Moeller, Moore, Heffernan, et al., Sioux City, IA, for Petitioner.
Michael Joseph Lang, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On December 26, 2019, Willa K. Lau (“Petitioner”), filed a petition under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”),² 42 U.S.C. § 300aa-10 et seq. (2018), alleging that due to an influenza (“flu”) vaccine administered on October 29, 2018, she developed Guillain-Barré syndrome (“GBS”). Petition at Preamble (ECF No. 1). More specifically, Petitioner asserts that the flu vaccination caused her GBS which caused “her left-sided facial paralysis.” Joint Prehearing Submission (“Joint Submission”), filed Apr. 10, 2023, at 1 (ECF No. 84). Respondent argued against compensation, stating “this case is not

¹ Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims’ website and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc> in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) (“Vaccine Act” or “the Act”). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

appropriate for compensation under the terms of the Act.” Respondent’s Report (“Resp. Rept.”) at 2 (ECF No. 26).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards, the undersigned finds Petitioner has provided preponderant evidence that her flu vaccine caused her GBS and left-sided facial paralysis, satisfying Petitioner’s burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

I. ISSUES TO BE DECIDED

The parties dispute diagnosis. Joint Submission at 1. Petitioner asserts that she suffered GBS, “which caused her left-sided facial paralysis.” Id. Respondent disagrees and “contends that [P]etitioner’s presentation [was] not consistent with GBS.” Id.

In her petition, Petitioner asserts a Table Claim for GBS after the flu vaccination. Petition at ¶ 29. Petitioner also alleges a causation-in-fact claim for GBS. Id. at ¶ 30. And in their joint submission, the parties agree that they dispute causation. Joint Submission at 2. Petitioner asserts her condition was caused by the flu vaccine administered to her on October 29, 2018. Id. Respondent disagrees and argues Petitioner failed to provide preponderant evidence that she suffered GBS or that her left-sided facial paralysis was caused by the flu vaccine. Id. Respondent also contends there was an alternate cause for Petitioner’s illness, unrelated to vaccination, asserting that “[P]etitioner’s Warthin’s tumor [was] the likely cause of [her] facial paralysis.” Id.

II. BACKGROUND

A. Medical Terminology

GBS is “characterized by a classical triad of progressive motor weakness, areflexia,³ and

³ Areflexia refers to the “absence of reflexes.” Areflexia, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=4035> (last visited Mar. 11, 2024).

albuminocytologic dissociation.”⁴ Resp. Exhibit (“Ex.”) A, Tab 16 at 1.⁵ “Cranial nerve^[6] palsies are frequent in GBS. Among cranial nerve palsies in GBS, facial nerve^[7] palsy is the most common[,] affecting around half of the cases. Facial palsy in GBS is usually bilateral and less frequently unilateral in adults.” Id. Although “cranial nerve involvement in GBS is common,” there are few studies focusing on it. Resp. Ex. A, Tab 13 at 3.⁸ “Many . . . clinicians [do not] look for the cranial nerve involvement” unless a patient complains of it. Id. at 3-4.

In addition to facial nerve palsy, there may be involvement of other cranial nerves, including the “lower cranial nerves, IX, X, XI, and XII.” Resp. Ex. A, Tab 16, at 3. Bulbar palsy⁹ can occur with facial palsy, and is characterized by dysphagia, “difficulty swallowing, dysphonia,^[10] and/or shoulder weakness.” Id. Some patients with signs of bulbar palsy may develop respiratory paralysis, requiring respiratory system support. Id.

⁴ Albuminocytologic dissociation is the “increase of protein with normal cell count in the spinal fluid.” Albuminocytologic Dissociation, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=71273> (last visited Mar. 11, 2024).

⁵ Kamal Sharma et al., Guillain-Barré Syndrome with Unilateral Peripheral Facial and Bulbar Palsy in a Child: A Case Report, 7 SAGE Open Med. Case Reps. (2019).

⁶ Cranial nerves are “the twelve pairs of nerves that are connected with the brain, including the nervi olfactorii (I), and the opticus (II), oculomotorius (III), trochlearis (IV), trigeminus (V), abducens (VI), facialis (VII), vestibulocochlearis (VIII), glossopharyngeus (IX), vagus (X), accessorius (XI), and hypoglossus (XII).” Nervi Craniales, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=92255> (last visited Mar. 11, 2024).

⁷ The facial nerve, or seventh cranial nerve, “consist[s] of two roots: a large motor root, which supplies the muscles of facial expression, and a smaller root, the nervus intermedius.” Nervus Facialis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=92293> (last visited Mar. 11, 2024). The nervus intermedius, or intermediate nerve, “joins the main root at, or merges with, the geniculate ganglion at the geniculum of the facial nerve; it contributes parasympathetic and special sensory fibers to the facial nerve.” Nervus Intermedius, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=92313> (last visited Mar. 11, 2024).

⁸ Amita Bhargava et al., A Study of Guillain-Barré Syndrome with Reference to Cranial Neuropathy and its Prognostic Implication, 5 J. Neurosciences Rural Prac. S43 (2014).

⁹ Bulbar palsy or bulbar weakness “refers to bilateral impairment of function of the lower cranial nerves IX, X, XI, and XII, which occurs due to . . . bilateral lesions of the lower cranial nerves outside the brain stem.” Nat’l Insts. Health, Bulbar Palsy, Nat’l Libr. Med., <https://www.ncbi.nlm.nih.gov/medgen/898626> (last visited Mar. 11, 2024).

¹⁰ Dysphonia is “any impairment of voice; a speech disorder or other difficulty in speaking.” Dysphonia, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15269> (last visited Mar. 11, 2024).

Warthin's tumor is a "benign tumor of the parotid gland"¹¹ characterized by cystic spaces lined by tall, columnar, eosinophilic epithelial cells, overlying a lymphoid tissue-containing stroma." Adenolymphoma, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=951> (last visited Mar. 11, 2024). It is generally a "[n]on-malignant disease of the parotid gland," and "rarely associated with facial nerve palsy." Resp. Ex. B, Tab 7 at 2.¹² "Facial nerve paralysis associated with a parotid mass suggests the presence of a malignant neoplasm." Id. at 1.

B. Procedural History

Petitioner filed her petition and medical records¹³ on December 26, 2019. Petition; Pet. Exs. 1-37. Respondent filed his Rule 4(c) Report, arguing against compensation, on October 29, 2020. Resp. Rept. at 2.

Petitioner filed an expert report from Dr. Salvatore Napoli on May 11, 2021. Pet. Ex. 47. Respondent filed expert reports from Dr. Dara Jamieson and Dr. Douglas Bigelow on October 25, 2021. Resp. Exs. A-B. Petitioner filed a supplemental expert report from Dr. Napoli on March 4, 2022. Pet. Ex. 49. And on June 17, 2022, Respondent filed supplemental expert reports from Dr. Jamieson and Dr. Bigelow. Resp. Exs. C-D.

On September 15, 2022, the undersigned held a Rule 5 conference. Rule 5 Order dated Sept. 15, 2022 (ECF No. 67). The undersigned preliminary found Petitioner had a "mild sensory neuropathy and syncope episode concerning for autonomic neuropathy," but needed additional information for any finding as to causation. Id. at 2. Accordingly, Petitioner filed a supplemental expert report from Dr. Napoli on January 27, 2023. Pet. Ex. 64.

Respondent indicated he was not willing to engage in settlement discussions and the parties agreed to resolve entitlement through a ruling on the record. Pet. Joint Status Rept., filed Feb. 8, 2023 (ECF No. 82). Petitioner filed her motion for a ruling on the record on April 10, 2023. Pet. Motion for Ruling on the Record ("Pet. Mot."), filed Apr. 10, 2023 (ECF No. 85). Respondent filed a response on June 9, 2023, and Petitioner filed a reply on July 10, 2023. Resp. Response to Pet. Mot. ("Resp. Response"), filed June 9, 2023 (ECF No. 89); Pet. Reply in Support of Pet. Mot. ("Pet. Reply"), filed July 10, 2023 (ECF No. 90).

The matter is now ripe for adjudication.

¹¹ The parotid gland is "the largest of the three glands occurring in pairs, which together with numerous small glands in the mouth constitute the salivary glands; it is located below the zygomatic arch, below and in front of the external acoustic meatus." Glandula Parotidea, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=78815> (last visited Mar. 11, 2024).

¹² Gino Marioni et al., Facial Nerve Paralysis Secondary to Warthin's Tumour of the Parotid Gland, 117 J. Laryngology & Otology 511 (2003).

¹³ Petitioner continued to file medical records throughout the course of litigation.

C. Factual History

1. Summary of Medical Records¹⁴

a. Pre-Vaccination and Vaccination History

Petitioner's pre-vaccination medical history is significant for, among other things, chronic pain, chronic headaches, asthma, bowel obstruction, cervical cancer, thyroid cancer, hypertension, and hyperlipidemia. Pet. Ex. 20 at 20, 85-87; Pet. Ex. 23 at 8-9; Pet. Ex. 36 at 82. Moreover, Petitioner smoked more than two packs of cigarettes per day for an unspecified amount of time before quitting in 2006. Pet. Ex. 21 at 7.

Most relevant to the instant claim, Petitioner had a pre-vaccination history of a Warthin's tumor of the left parotid gland confirmed by biopsy in 2014, and was followed for that condition by otolaryngologist, Dr. David Goldenberg, at Hershey Medical Center. Pet. Ex. 37 at 350, 353.

In May 2017, Petitioner complained to her primary care provider, Dr. John Schwartz, D.O., about headaches that were similar to those she had when the tumor was biopsied. Pet. Ex. 20 at 66-67.

On June 21, 2017, Petitioner consulted with otolaryngologist, Dr. Bret T. Sobota, for recent frontal headaches with retro-orbital pressure. Pet. Ex. 21 at 6-9. On examination, Petitioner had palpable tenderness across the forehead and temples. *Id.* at 8. Petitioner's computed tomography ("CT") scan on June 29, 2017 revealed, among other things, acute right maxillary sinusitis and marked thickening of the left frontal and nasofrontal recess with ethmoid/maxillary sinus disease. *Id.* at 10-11.

At a follow-up visit with Dr. Sobota on July 21, 2017, Petitioner reported that her facial pain and headaches improved with taking antibiotics for her sinus infection and taking carisoprodol (a muscle relaxer that blocks pain sensations between the nerves and the brain). Pet. Ex. 21 at 13-15. Petitioner additionally reported that she remained undecided about proceeding with a resection of her Warthin's tumor (surgical procedure to remove all or part of the tumor), and that she was planning to proceed with the surgery if her left facial pain and pressure had not resolved with her treatment regimen. *Id.* at 15. Petitioner was advised to follow up with Dr. Goldenberg for possible resection of her Warthin's tumor if her symptoms recurred. *Id.*

On October 2, 2017, Petitioner consulted with Dr. Goldenberg for her Warthin's tumor. Pet. Ex. 3 at 145. At that time, Petitioner reported that she developed new-onset left-sided headaches and wanted her tumor mass removed. *Id.* She additionally reported a history of two

¹⁴ This summary of facts is largely taken from Respondent's Brief, as the undersigned finds it to be accurate. *See* Resp. Response at 3-17. Additionally, the expert reports also contain summaries of the medical records. Pet. Ex. 47 at 2-3; Resp. Ex. A at 2-10; Resp. Ex. B at 3-17.

prior occurrences of Bell's palsy¹⁵ on the left side of her face, which subsequently resolved.¹⁶ Id. Dr. Goldenberg attributed Petitioner's Bell's palsy symptoms to the Warthin's tumor. Id. Petitioner's examination was notable for a slight lag in closure of her left eye that was chronic, but the rest of her facial nerve motion was intact. Id. A non-contrast CT scan of the neck conducted on that same date revealed no significant progression over the preceding two years of Petitioner's Warthin's tumor. Id. at 16-17. Dr. Goldenberg planned to proceed with excision of the deep lobe parotid tumor. Id. at 145.

Petitioner left a message with a surgery scheduling staff member in Dr. Goldenberg's office on December 27, 2017. Pet. Ex. 4 at 10. At that time, Petitioner reported that she was having knee surgery in January 2018, and that the frequency of her headaches had lessened, leading her to question the necessity of the excision. Id. Petitioner relayed, however, that she wanted to continue yearly follow-up visits with Dr. Goldenberg. Id.

Petitioner received two doses of the shingles vaccine on April 30, 2018, and on August 7, 2018.¹⁷ Pet. Ex. 24 at 12-13; Pet. Ex. 20 at 8.

On September 10, 2018, Petitioner consulted with Dr. Schwartz and reported a gradual onset of her third bout of Bell's palsy over the prior few days involving her right side.¹⁸ Pet. Ex. 20 at 90-91. Petitioner reported that her prior bouts of Bell's palsy symptoms came on suddenly, in contrast to her current onset. Id. at 90. She additionally complained of left-sided headaches similar to those she suffered in the past and had an associated feeling of pressure behind her left eye. Id. Petitioner's examination revealed right-sided facial paralysis with an inability to "crinkle" her right forehead. Id. at 90-91. Petitioner was prescribed an erythromycin ophthalmic ointment for her right eye, in addition to valacyclovir (an antiviral medication), and a prednisone taper over nine days. Id. at 91. Petitioner was advised to follow up in two weeks. Id.

Petitioner had a follow-up visit with Dr. Schwartz on September 24, 2018, at which time she reported that she had no appreciable improvement in her symptoms, that she was unable to

¹⁵ Bell's palsy is "unilateral facial paralysis of sudden onset, due to lesion of the facial nerve and resulting in characteristic distortion of the face." Bell Palsy, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=95779> (last visited Mar. 11, 2024).

¹⁶ Petitioner's 2018 records indicate that her first incident of Bell's palsy occurred "15 years ago," and her second recurrent Bell's palsy happened "a couple years ago." Pet. Ex. 3 at 191.

¹⁷ The shingles vaccine is a non-covered vaccine on the Vaccine Injury Table and therefore, while it is sometimes discussed by the experts, this Ruling does not address any injury alleged to be associated with it. See 42 C.F.R. § 100.3.

¹⁸ The petition does not allege that Petitioner's right-sided facial weakness was caused by her flu vaccination and the parties have not asked the undersigned to adjudicate its cause. Thus, while Petitioner's right-sided facial palsy is described in the medical records and discussed by the experts, the undersigned does not adjudicate the cause of Petitioner's right-sided facial palsy herein. The undersigned's Ruling is strictly limited to the cause of Petitioner's left-sided facial palsy.

close her right eye, and that she had significant drooping of her right face. Pet. Ex. 20 at 93-94. Petitioner further complained of pain in the right side of her body, and Dr. Schwartz considered a neurology evaluation. Id. Dr. Schwartz advised that Petitioner proceed with a magnetic resonance imaging (“MRI”) of the brain if she found no improvement in her symptoms over the following two weeks. Id. at 94.

Petitioner had a follow-up visit with Dr. Schwartz on October 8, 2018, and reported that she had some improvement in her right-sided Bell’s palsy symptoms, and her symptoms appeared less pronounced on examination. Pet. Ex. 20 at 95-96. Dr. Schwartz recommended that Petitioner undergo an MRI of the brain and the parotid gland if she did not markedly improve in three weeks. Id. at 96.

On October 18, 2018, Petitioner visited Dr. Goldenberg for her Warthin’s tumor. Pet. Ex. 3 at 191. A CT scan conducted at that time revealed that there was no progression or change in her Warthin’s tumor. Id. Petitioner reported a new onset of right-sided Bell’s palsy since September 2018, with sensitivity and hyperesthesia (increased sensitivity) in the temple, earlobe, and mastoid region. Id. Petitioner’s examination revealed a complete facial nerve paralysis on the right without vesicles on the ear, with some hyperesthesia and sensitivity on the temple. Id. Petitioner was referred to a facial nerve otolaryngologist, Dr. Jessyka Lighthall. Id.

Petitioner consulted Dr. Lighthall on October 26, 2018 and reported that she had an acute right facial paralysis develop in September 2018, which occurred about two weeks after her shingles vaccination. Pet. Ex. 4 at 41-42. Petitioner’s examination was notable for complete facial movement on the left, slight movement of the right brow, incomplete right eye closure, right ectropion and epiphora (eyelid dysfunctions), and no movement of her midface. Id. at 42. Petitioner was given a humidification chamber for her symptoms, and she was advised to continue using refresh drops and to use an ophthalmic lubricant at night. Id. Dr. Lighthall recommended that Petitioner follow up in three months. Id.

During a follow-up visit with Dr. Schwartz on October 29, 2018, Petitioner received the subject flu vaccination at the age of 72. Pet. Ex. 20 at 104.

b. Post-Vaccination History

i. November 2018 Through January 2019

Petitioner presented to Hanover Hospital emergency department (“ED”) on November 2, 2018, four days after her flu vaccination, and reported a constant headache involving the back of her head, forehead, and left cheek that began the night prior, as well as elevated blood pressure. Pet. Ex. 25 at 428. On examination, Petitioner had some right sclera irritation, drooping of the right side of the mouth, but had no sensory or strength deficits. Id. at 429. Petitioner was assessed with hypertension and left trigeminal neuralgia and was prescribed prednisone prior to being discharged in the early hours of November 3, 2018. Id. at 433.

Petitioner returned to Hanover Hospital ED several hours later, on November 3, 2018, complaining of persistent left-sided headaches and facial pain, nausea, vomiting, and generalized

weakness. Pet. Ex. 36 at 28-31. Petitioner reported feeling as if she had left-sided Bell's palsy. Id. at 28. Her blood pressure remained elevated and left facial weakness was noted. Id. at 29-30. Petitioner's speech was coherent, and her motor strength was equal bilaterally without weakness. Id. at 30. Petitioner was suspected of having trigeminal neuralgia and received Decadron. Id. A brain MRI revealed widespread disease with right maxillary acute sinusitis, but no abnormality involving the trigeminal nerves was noted. Id. at 30-31; Pet. Ex. 37 at 435. Petitioner's head CT revealed nonspecific prominence of the bilateral ophthalmic veins and increased intracranial pressure. Pet. Ex. 36 at 30; Pet. Ex. 37 at 433. Petitioner was discharged from Hanover Hospital ED with instructions to follow up with her primary care provider. Pet. Ex. 36 at 31.

On November 3, 2018, Petitioner had a weekend phone consultation with an otolaryngology resident affiliated with Hershey Medical Center regarding her recent ED visit at Hanover Hospital. Pet. Ex. 4 at 44. The otolaryngology resident advised an urgent evaluation at Hershey Medical Center, but Petitioner was unable to go until two days later as she lived 90 minutes away. Id. In the interim, Petitioner's prednisone taper was prolonged, other measures to protect the eye were advised, and Zofran was prescribed for nausea. Id.

In a follow-up phone call with the otolaryngology resident on November 4, 2018, Petitioner reported that her pain had largely resolved with gabapentin, and an MRI of the internal auditory canal and facial nerve was scheduled for the coming days. Pet. Ex. 13 at 76.

Petitioner had a consultation with Dr. Lighthall on November 5, 2018. Pet. Ex. 10 at 34-35. In relevant part, Petitioner reported a history of Bell's palsy, with the first bout occurring fifteen years prior, and the second bout occurring several years prior on the left side of her face, which resolved within two weeks. Id. at 34. Petitioner reported that her recent occurrence of paralysis associated with her Bell's palsy was the longest she had experienced. Id. Petitioner additionally reported that she received the flu vaccination approximately three days prior, and that she had a mild sore throat with chronic postnasal drainage due to her chronic sinusitis. Id. Petitioner denied numbness or tingling at that time. Id. Petitioner's examination was notable for a hoarse quality to her voice, intact facial sensation, and total paralysis of her face bilaterally. Id. Petitioner's assessment was "bilateral facial paralysis, recurrent, in the setting of post-immunization." Id. at 35. The plan was to admit Petitioner to the hospital for an aggressive work up, as there was concern regarding autoimmune and neurologic involvement, including GBS. Id.

Petitioner was hospitalized from November 5, 2018 through November 12, 2018. Pet. Ex. 10 at 1. On November 5, 2018, Petitioner underwent MRIs of the brain, face, and neck, which an otolaryngologist noted were negative for stroke or seventh cranial nerve pathology. Pet. Ex. 7 at 49-50; Pet. Ex. 5 at 15.

On November 6, 2018, Petitioner underwent a bilateral upper eyelid platinum weight placement for her "bilateral facial paralysis of unknown origin," and to assist Petitioner with closing her eyes. Pet. Ex. 10 at 41-42. On that same date, Petitioner also underwent a lumbar puncture under general anesthesia. Id. at 41-42, 63.

Petitioner was evaluated by a neurologist, Dr. Chichun Sun, D.O., on November 6, 2018.

Pet. Ex. 4 at 103-04, 173-77. Petitioner “complained of trouble swallowing her own saliva, but was okay drinking water” in the hours prior to her appointment. Id. at 103. Review of systems included imbalance for three days and numbness of face bilaterally. Id. Examination revealed “[b]ilateral upper and lower face severe [paralysis], cannot smile, puff out cheeks, or wrinkle forehead.” Id. at 174. Motor examination found 3/5 in shoulder abduction, which Petitioner reported was chronic for two years and attributed to pain. Id. Reflexes were biceps 1+, brachioradialis 2+, triceps 1+, patellar 0, and Achilles 0. Id. Petitioner’s differential diagnoses included, among other things, GBS “in the setting of recent vaccinations,” seventh cranial nerve palsy secondary to known left Warthin’s tumor, Tolosa Hunt syndrome (rare disorder characterized by severe periorbital headaches and decreased and painful eye movements), and brainstem stroke. Id. at 104.

On November 7, 2018, Petitioner saw Dr. Sun, who noted Petitioner’s lumbar puncture results, revealing cerebrospinal fluid (“CSF”) protein levels of 46 mg/dL, and deemed those results to be insignificant. Pet. Ex. 4 at 169-72. Petitioner reported trouble swallowing her own saliva but was able to swallow water. Id. at 169. Petitioner’s examination now showed areflexia (biceps 0, brachioradialis 0, triceps 0, patellar 0, and Achilles 0) with normal strength throughout, with the exception of shoulder abduction. Id. at 170. The working diagnosis was GBS with Bell’s palsy in setting of recent vaccinations. Id. at 171. Petitioner was started on intravenous immunoglobulin (“IVIG”) therapy for two days. Id. at 172.

Petitioner had physical therapy (“PT”) and occupational therapy (“OT”) evaluations on November 7, 2018. Pet. Ex. 4 at 153-59. Those evaluations noted that Petitioner was independent with her activities of daily living. Id. Petitioner reported that gabapentin made her slightly unsteady, but that she could ambulate independently in her room and hallways without any problems. Id. at 156, 158. In-patient skilled therapy was therefore deemed unnecessary at that time. Id. at 159. Petitioner received two doses of IVIG, without complication, on November 7 and 9. Id. at 165, 172. Petitioner’s neurology consultation on November 9, 2018, revealed that she was areflexic and had normal strength and intact sensation. Id. at 160-61. No further IVIG was recommended, but the working diagnosis remained GBS with Bell’s palsy in the setting of recent vaccinations. Id. at 163.

Petitioner was discharged on November 12, 2018. Pet. Ex. 10 at 1-7. At the time of discharge, Petitioner’s principal diagnosis was facial nerve paralysis, and other diagnoses included exposure keratitis (inflammation of the cornea) and chronic kidney disease. Id. at 1-2. Her discharge assessment did not include a diagnosis of GBS. Id. Petitioner was discharged on a prednisone taper, gabapentin, fioricet (medication used to treat tension headaches), tramadol (pain reliever), and her usual pre-hospitalization medications. Id. at 3-4.

On November 14, 2018, Petitioner underwent a CT-guided biopsy of the left parotid mass. Pet. Ex. 9 at 123-24. Petitioner’s cytologic diagnosis was Warthin’s tumor with acute inflammation and necrosis suggestive of an associated inflammatory process, but a clinical correlation diagnosis was required. Id.

On November 26, 2018, Petitioner consulted Dr. Schwartz for a suspected sinus infection. Pet. Ex. 20 at 105-06. Petitioner’s examination revealed tenderness over the maxillary

sinuses, and she was prescribed augmentin (an antibiotic). Id.

On December 3, 2018, Petitioner consulted Dr. Lighthall and reported that her vision and eyes were significantly improved after the weight placements. Pet. Ex. 8 at 9-10. Petitioner additionally reported that she experienced tightness and discomfort in the left mid-facial region and was doing facial exercises. Id. On examination, Petitioner was noted to be regaining facial muscle tone more on her left side versus her right, was noted to have some right eyebrow movement, and some left lower branch movement. Id. at 10. Additionally, Petitioner had hyperkinesis (uncontrollable muscular movements) and synkinesis (involuntary muscle contractions) on her left side, which was causing tightness in her mid-face and neck. Id. Dr. Lighthall's assessment of Petitioner indicated

[Petitioner] has bilateral facial paralysis with a remote history of Bell's palsy and both of these episodes occurred after immunizations of both shingles and the flu. I recommend she not proceed with any additional flu or shingles immunizations. All other workup was negative for other source and so she has a presumptive diagnosis of [GBS], which was treated. Her picture is muddled somewhat due to the left deep lobe parotid tumor.

Id. at 10. Petitioner was referred to a speech pathologist. Id.

ii. February 2019 Through April 2019

Petitioner saw Dr. Lighthall on February 8, 2019 and reported more motion on the right side of her face than the left side and new numbness and tingling in her bilateral extremities and hands. Pet. Ex. 7 at 128-29. Petitioner's examination revealed left greater than right facial weakness, and hyper-elevation of the right brow due to hyperkinesis of the right frontalis muscle. Id. at 129. Petitioner additionally had minimal brow movement on the left with brow ptosis (dropping of the eyebrow lower than normal), while her lower eyelids were gaining tone, and her upper eyelid weights provided full eyelid closure. Id. Petitioner was referred to physical therapy for her facial symptoms and to neurology. Id.

On February 11, 2019, Petitioner consulted with a plastic surgeon, Dr. Cathy Henry. Pet. Ex. 7 at 131-32. Dr. Henry noted that Petitioner's bilateral facial nerve paralysis "was thought [to be] secondary to [GBS] following flu and s[h]ingles vaccinations." Id. at 131. Dr. Henry noted that since Petitioner's last visit in December 2018, Petitioner had significant recovery of muscle function, with good symmetry at rest and without notable difficulty with synkinesis (involuntary facial contractions). Id. Petitioner's examination noted evidence of muscle function in all distributions, with the forehead being the weakest, and the right side being stronger than the left. Id. Dr. Henry advised Petitioner to continue facial nerve therapy exercises. Id.

Petitioner was seen by Dr. Lighthall in a follow-up visit on March 25, 2019. Pet. Ex. 7 at 104-05. Petitioner was noted to be recovering her facial nerve function but was developing hypertonicity (high muscle tone leading to an increased state of active muscle contraction) and synkinesis on the right side that had worsened since the last visit. Id. Petitioner was advised to

continue facial therapy, and Dr. Lighthall planned to give Petitioner Botox injections at the next visit to treat her facial spasms and increased facial muscle tone. Id. at 105.

iii. May 2019 Through September 2021

On May 1, 2019, Petitioner was seen in a neuromuscular clinic by Dr. Max Lowden. Pet. Ex. 7 at 69-70. In relevant part, Petitioner described numbness and tingling since January 2019 at the tops of her feet up to her knees that was persistent, and some forearm and hand tingling. Id. at 69. Petitioner reported no weakness or pain but did report some jerking activity of both arms and legs. Id. Petitioner's speech was noted to be fluent without hoarseness. Id. at 70. On examination, she had a normal sensory exam, absent reflexes in the bilateral lower extremities, trace reflexes in the bilateral upper extremities, decreased pin sensations in the left lower extremities, in addition to having normal strength and coordination. Id. Petitioner was observed to have bifacial weakness with weak eye closure, but she was able to wrinkle her forehead on her left side. Id. Dr. Lowden assessed Petitioner with "bilateral cranial neuropathy, specifically [seventh] cranial nerve palsies," in addition to numbness and tingling in the lower and upper extremities. Id. Dr. Lowden recommended that Petitioner undergo a variety of additional tests, such as an electromyography ("EMG") and nerve conduction study ("NCS") of the left upper and left lower extremity. Id. Dr. Lowden hoped to better assess whether Petitioner suffered from a mononeuritis multiplex neuropathy, versus chronic inflammatory demyelinating polyneuropathy ("CIDP"), versus other forms of polyneuropathy. Id.

Petitioner saw physician assistant ("PA") Marisa Zohner at Dr. Lowden's office on September 11, 2019. Pet. Ex. 29 at 1-3. In relevant part, PA Zohner noted that Petitioner's EMG study was remarkable for mild sensory polyneuropathy and was not consistent with CIDP. Id. at 1. At that visit, Petitioner reported that her numbness and tingling had progressed; it was distal to the left thigh and involved the left upper extremity. Id. Petitioner additionally reported some stiffness in her hands and pain along the thumbs into the wrists and forearms. Id. Petitioner was advised to provide an update in three-to-four weeks, and to follow up in six months. Id. at 3.

On September 27, 2019, Petitioner had a follow-up visit with Dr. Lighthall for her Bell's palsy. Pet. Ex. 32 at 1-2. Petitioner and her daughter reported that Petitioner had improved facial symmetry after Botox injections. Id. at 1. On examination, Dr. Lighthall observed an incomplete recovery of strength on the right side of Petitioner's face, and noted that, bilaterally, there was a mixed picture of hyperkinesis, weakness, synkinesis, and spasms. Id. at 2. Petitioner received an additional Botox injection. Id.

Dr. Lighthall followed up with Petitioner on January 10, 2020. Pet. Ex. 45 at 16-17. At that visit, Petitioner complained of increased eye closure and superior visual field obstruction secondary to weights, as well as mild swelling in the right eyelid. Id. at 16. Dr. Lighthall's assessment was "incomplete recovery on the right with bilateral mixed picture of persistent hyperkinesis, hypokinesis, and synkinesis." Id. at 17. Petitioner requested to delay further Botox treatments and requested removal of her eyelid weights. Id.

On January 16, 2020, Petitioner had a follow-up visit with Dr. Goldenberg. Pet. Ex. 40 at

244. At that time, she underwent a CT scan, which showed “interval decrease in the partially calcified deep [left] parotid tumor, now 1.5 x 1.5 cm with increased tissue hypodensity consistent with necrosis, reactive lymph nodes, multinodular goiter, and moderate to severe pansinusitis.” Pet. Ex. 45 at 14-15.

Petitioner’s bilateral upper eyelid weights were removed on February 13, 2020. Pet. Ex. 41 at 56.

On June 3, 2020, Petitioner had a follow-up visit with Dr. Lowden, who noted Petitioner’s problems with dizziness and cardiologic evaluations. Pet. Ex. 41 at 12-28. An examination revealed decreased sensation in Petitioner’s toes, a cautious gait, and a positive Romberg test consistent with sensory ataxia. Id. at 128.

On August 26, 2020, Petitioner underwent autonomic disorder testing, which revealed abnormal results. Pet. Ex. 62 at 19. A Qsweat analysis showed a non-length dependent pattern, low sweat volumes at proximal sites and normal at foot sites. Id. Her heart rate during deep breathing showed low values, which suggested a generalized disorder of Petitioner’s nervous system. Id.

Petitioner visited ophthalmologist Dr. Christopher Weller on September 30, 2020, for evaluation of her bilateral ptosis, facial paralysis, and visual field obstruction. Pet. Ex. 42 at 50. An examination at that time was notable for moderate dermatochalasis of both upper eyelids, diminished orbicularis muscle strength, decreased blink speed, lagophthalmos, and other decreased function of the eyelids. Id. at 52-53. Dr. Weller recommended continued Dysport therapy and discussed the possibility of surgery for Petitioner’s eyelid issues. Id. at 55.

Petitioner presented to Dr. Schwartz on November 16, 2020, and reported that she was no longer interested in receiving further care from specialists, as she did not believe Botox or other injections were providing any benefit. Pet. Ex. 46 at 11.

On November 27, 2020, Petitioner returned to Dr. Lighthall with complaints of occasional unsteadiness, dizziness, syncope, and falls. Pet. Ex. 42 at 9-10. Petitioner indicated she had been inconsistent with her home exercise and expressed a desire to stop all therapy. Id. at 9. Petitioner’s course of care was discontinued, and she agreed to follow up as needed. Id. at 10.

On April 18, 2021, Petitioner presented to Hanover Medical Group with complaints of shortness of breath over the previous five days. Pet. Ex. 60 at 9. She was referred to the ED where she was diagnosed with pneumonia pleural effusion of unknown etiology. See id. at 19. On May 17, 2021, Petitioner presented to Dr. Schwartz for follow-up after her hospitalization. Id.

Petitioner returned to Dr. Schwartz for a follow-up visit on September 15, 2021. Pet. Ex. 61 at 10. At that visit, Dr. Schwartz’s impression stated,

74-year-old woman with history of GBS in the past, treated with IVIG. There has

been resolution of that and no recurrence. Repeat EMG testing shows a mild sensory neuropathy. She had autonomic testing, which shows evidence of small fiber neuropathy. My concern is she has autonomic polyneuropathy of unknown etiology.

Id. at 11.

No other relevant records were filed.

2. Petitioner's Affidavit

Petitioner executed an affidavit on December 20, 2019. Pet. Ex. 1 at 4. Petitioner recalled that before the subject vaccination, she did not suffer from GBS and never experienced bilateral facial paralysis. Id. at ¶¶ 21, 23.

On October 29, 2018, Petitioner went to her primary care provider's office because she "had recently experienced right-sided facial droop." Pet. Ex. 1 at ¶ 4. At that visit, she received the flu vaccine. Id. at ¶ 3. Three days later, on November 2, Petitioner experienced "sudden left-sided facial paralysis along with excruciating facial nerve pain." Id. at ¶ 5. Petitioner was transported to the hospital via ambulance. Id. The initial impression of the ED doctors was that Petitioner "had hypertension and trigeminal neuralgia of the left side of [her] face." Id. at ¶ 6. She was sent home with prednisone. Id.

The next day, Petitioner continued to have "excruciating facial pain" and also experienced nausea, vomiting, and generalized weakness so she returned to the hospital. Pet. Ex. 1 at ¶ 7. Petitioner underwent CT and MRI scans, all of which were unremarkable besides a finding of acute sinusitis. Id. at ¶ 8. Petitioner was told she was "suffering from trigeminal neuralgia and was offered oxycodone for [her] pain, which [she] refused." Id.

After being released from the hospital, Petitioner made an appointment with Dr. Lighthall at the otolaryngology clinic on November 5, 2018. Pet. Ex. 1 at ¶¶ 9-10. Petitioner "began to experience memory difficulties and unsteadiness." Id. at ¶ 10. Dr. Lighthall advised Petitioner to be admitted to the hospital for an "'aggressive workup' of [her] bilateral facial paralysis." Id. Dr. Lighthall recommended Petitioner to undergo a surgery "where [Dr. Lighthall] would place eyelid weights in [Petitioner's] eyes to protect them as [Petitioner] could no longer close [her] eyes on [her] own." Id. at ¶ 11.

Petitioner continued to have left-sided facial pain and paralysis. Pet. Ex. 1 at ¶ 12. Neurology evaluated her on November 6, 2018 where she was diagnosed with GBS. Id. They also recommended Petitioner undergo a lumbar puncture. Id. Later that day, Petitioner underwent the eyelid weigh surgery and a lumbar puncture. Id. at ¶ 13. The lumbar puncture was unremarkable but Petitioner was "still told that they thought [she] had GBS and that [she] should undergo infusion treatment." Id. at 14. Petitioner received her first dose of IVIG that day and was given gabapentin. Id. Petitioner continued to receive IVIG treatment until discharge on November 12, 2018. Id. at ¶ 15.

Petitioner continued to seek treatment for the residual effects of GBS. Pet. Ex. 1 at ¶ 16. As of the date Petitioner executed this affidavit, Petitioner still had facial paralysis and tightness; she also developed “severe dry eye syndrome.” Id. Petitioner continued taking gabapentin daily. Id.

3. Treating Physician’s Statements in the Medical Records

In addition to the facts set forth above, the following chart contains relevant statements from Petitioner’s treating specialists, Dr. Lighthall (otolaryngology) and Dr. Sun (neurology), related to Petitioner’s diagnosis of GBS and flu vaccine causation.

Date	Medical Record Entry	Exhibit
10-29-2018	Flu vaccination	Pet. Ex. 20 at 104
11-05-2018	Dr. Lighthall – Petitioner had hoarse quality to voice, intact facial sensation, and total paralysis of face bilaterally. Assessment was bilateral facial paralysis, recurrent, post-vaccination. The plan was to admit to hospital for “aggressive work up” due to “concern[] for autoimmune and neurological involvement[,] including [GBS].”	Pet. Ex. 10 at 34-35; Pet. Ex. 4 at 120-21
11-06-2018	Dr. Sun – Review of systems included imbalance for three days and numbness of face bilaterally. Examination revealed bilateral upper and lower severe face paralysis and decreased reflexes. Differential diagnoses included “[GBS] in the setting of recent vaccinations” and seventh cranial nerve palsy secondary to Warthin’s tumor.	Pet. Ex. 4 at 103-04, 173-77
11-07-2018	Dr. Sun – Petitioner reported trouble swallowing her own saliva but was able to swallow water. Examination revealed bilateral upper and lower severe face paralysis and areflexia. “Working diagnosis [was] [GBS] with Bell’s palsy in the setting of recent vaccinations.” IVIG was ordered for two days.	Pet. Ex. 4 at 169-72
11-09-2018	Dr. Sun – Examination revealed areflexia, normal strength and intact sensation. “Working diagnosis [was] [GBS] with Bell’s palsy in the setting of recent vaccinations.”	Pet. Ex. 4 at 161-63
12-03-2018	Dr. Lighthall – “Bilateral facial paralysis with a remote history of Bell’s palsy” and both episodes occurred after shingles and flu vaccinations. All other workup was negative for other source. “Presumptive diagnosis of [GBS] . . . her picture is muddled somewhat due to [] left deep lobe parotid tumor.”	Pet. Ex. 8 at 9-10
02-19-2019	Dr. Lighthall – Follow-up for bilateral facial paralysis thought secondary to GBS status post IVIG November 2018. Petitioner started to regain function. Examination revealed bilateral facial weakness, worse on the left than the right.	Pet. Ex. 7 at 128-29
03-25-2019	Dr. Lighthall – Follow-up for bilateral facial paralysis secondary to GBS. Assessment was bilateral facial paralysis and synkinesis.	Pet. Ex. 7 at 104-05

D. Expert Qualifications and Opinions

1. Expert Qualifications

a. Petitioner's Expert, Dr. Salvatore Q. Napoli

Dr. Napoli is a board-certified neurologist licensed in Massachusetts. Pet. Ex. 47 at 1. He received his M.D. from Albany Medical College followed by an internship and neurology residency at Albany Medical Center. Pet. Ex. 48 at 2. Dr. Napoli completed clinical fellowships in neurophysiology, neuroimmunology and multiple sclerosis ("MS") in Boston, Massachusetts. Id. at 1-2. Dr. Napoli is currently the President, Owner, and Medical Director of Neurology Center of New England and MS Center of New England. Id. at 1. He is also on the medical staff at two other hospitals. Id. In the last five years, Dr. Napoli has "seen and treated approximately 10-40 patients with CIDP, [GBS], and other autoimmune peripheral nerve disorders." Pet. Ex. 47 at 2. He has published several articles in peer-reviewed journals, as well as abstracts and presentations, focused on demyelinating diseases, the field of neurology generally, and the neuroimmunology component of the treatment of central nervous system disorders. Id. at 1; Pet. Ex. 48 at 6-8.

b. Respondent's Expert, Dara G. Jamieson

Dr. Jamieson is a board-certified neurologist licensed in New York. Resp. Ex. A, Tab 1 at 2. She received her medical degree from the University of Pennsylvania, followed by a neurology residency and a cerebrovascular fellowship at the University of Pennsylvania Hospital. Resp. Ex. A. at 1. Dr. Jamieson was a practicing neurologist for 32 years before transitioning to a voluntary faculty appointment in 2018. Id. She is currently a Clinical Associate Professor of Neurology at Weill Cornell Medicine, where she teaches medical students in neurology courses and clinical inpatient clerkships, as well as lectures to residents and fellows. Id. She has also lectured extensively nationally and internationally on neurological topics. Id. at 2; Resp. Ex. A, Tab 1 at 4-10. Dr. Jamieson serves on several editorial boards, including the Journal of Neuroimmunology, Current Treatment Opinions in Neurology, and Neurology Alert. Resp. Ex. A. at 2. She has authored or co-authored numerous publications in peer reviewed journals as well as authored books and book chapters on various neurological topics. Id.; Resp. Ex. A, Tab 1 at 13-14.

c. Respondent's Expert, Dr. Douglas C. Bigelow

Dr. Bigelow is board certified in otolaryngology head and neck surgery, with a subspecialty of neurotology.¹⁹ Resp. Ex. B at 3; Resp. Ex. B, Tab 1 at 2. He received his M.D. from the University of Minnesota School of Medicine, and completed an otolaryngology-head and neck surgery residency at Washington University, St. Louis. Resp. Ex. B, Tab 1 at 1. He is currently an Associate Professor in the Department of Otorhinolaryngology: Head and Neck

¹⁹ Neurotology is the "neurological study of the ear." Neurotology, Merriam-Webster Dictionary Online, <https://www.merriam-webster.com/medical/neuro-otology> (last visited Mar. 11, 2024).

Surgery at the University of Pennsylvania School of Medicine. Id. at 2. He is also the Director of the Division of Otolaryngology/Neurotology at the University of Pennsylvania Medical Center in Philadelphia. Id. Dr. Bigelow has “over thirty years of experience as an attending physician managing patients with otology problems, facial weakness” and more “in a university tertiary care setting.” Resp. Ex. B at 2. As part of his practice, he “routinely review[s] and interpret[s] diagnostic radiologic imaging related to the ears, facial nerve, skull base and the head & neck on a daily basis.” Id.

2. Expert Opinions

a. Petitioner’s Expert, Dr. Salvatore Q. Napoli²⁰

i. Diagnosis of GBS

Dr. Napoli opined that Petitioner had “bilateral facial diplegia^[21] consistent with a variant of [GBS]” after vaccination. Pet. Ex. 47 at 3. Although Dr. Napoli opined that Petitioner’s clinical course was consistent with a Table claim for GBS, he noted that she did not have some findings that are usually associated with the illness. Id. For example, he noted that Petitioner did not have “extremity weakness and other findings associated with [GBS].” Id. at 5. However, this did not change his opinion that the Petitioner had a “variant of [GBS].” Id.

ii. Table Claim for GBS

Dr. Napoli asserted that Petitioner met the Table criteria for GBS because the time frame from vaccination to onset of her first symptom (left facial droop) was between three and 42 days. Pet. Ex. 47 at 3. Specifically, Dr. Napoli opined that Petitioner received the flu vaccine on October 29, and on November 3, she had left facial droop. Id. He stated “[t]his is consistent with bilateral facial diplegia consistent with [GBS].” Id.

Next, Dr. Napoli opined that the interval between the appearance of her symptoms and the nadir of her weakness was between 12 hours and 28 days, and again, he noted this clinical course is consistent with the Table criteria. Pet. Ex. 47 at 3. He explained that Petitioner’s facial diplegia began by November 2, and worsened over the next 12 hours to paralysis. Id. He further states that her condition plateaued within 28 days, and that although she received treatment, she did not significantly improve. Id.

Lastly, Dr. Napoli asserted there was no alternative cause for Petitioner’s diplegia noted by any of Petitioner’s physicians, and that again, this was consistent with the Table injury of GBS. Pet. Ex. 47 at 3. Dr. Napoli disagreed with Respondent’s expert, Dr. Bigelow, that Petitioner’s Warthin’s tumor caused her left-sided facial weakness. Pet. Ex. 49 at 2. Instead, Dr. Napoli agreed with the opinions of Petitioner’s treating physicians who assessed Petitioner with

²⁰ Petitioner filed three expert reports authored by Dr. Napoli. Pet. Exs. 47, 49, 64.

²¹ Diplegia is a “paralysis affecting like parts on both sides of the body.” Diplegia, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=14328> (last visited Mar. 11, 2024).

GBS after vaccination. Pet. Ex. 64 at 2.

In June 2020, Petitioner was seen by Dr. Lowden, who noted that she had decreased sensation in the feet, cautious gait, and positive Romberg test, all consistent with sensory ataxia. Pet. Ex. 42 at 121-23. In 2021, her Qsweat test was abnormal, and her EMG showed small fiber neuropathy. Pet. Ex. 62 at 19. She was diagnosed with “autonomic polyneuropathy of unknown etiology.” Pet. Ex. 61 at 11. Based on his review of these later records, Dr. Napoli opined that Petitioner’s mild sensory neuropathy and syncopal episodes that occurred in 2020-2021, and her EMG results in 2021, were “more likely than not unrelated to [her] vaccinations” or prior episodes of facial paresis. Pet. Ex. 64 at 1-2.

iii. Causation: Althen Prong One

Dr. Napoli offered a causation-in-fact opinion based on the theory of molecular mimicry. Pet. Ex. 47 at 4. He explained that vaccines are intended to stimulate an immune response when administered. Id. Citing the paper by Lahesmaa et al.,²² he explained the mechanism of molecular mimicry. Id. (citing Pet. Ex. 51). If a viral antigen in the vaccine shares protein sequences (homologies) with a host antigen (in the vaccinee), then “an immune response will be directed at both the injected antigens and host antigen leading to an autoimmune response.” Id. (citing Pet. Ex. 51 at 1).

In support of the theory of molecular mimicry, Dr. Napoli cited well known studies that support molecular mimicry as a sound and reliable immune response that explains how vaccines, including the flu vaccine, can cause GBS.

Schonberger et al.²³ observed that there was an increase in GBS following the flu vaccine. Pet. Ex. 58 at 1. Schonberger et al. reviewed case reports from the Centers for Disease Control and Prevention (“CDC”) of GBS after flu vaccine administration and found, on average, an onset between two and three weeks. Id. As to etiology, the authors discussed the mechanism of an immunopathologic reaction leading to cellular changes. Id. at 18. They related it to immunization causing allergic encephalomyelitis via molecular mimicry. Id.

Haber et al.²⁴ also reported increased cases of GBS following the flu vaccine. Pet. Ex. 53 at 1. The authors reported an onset of GBS following the flu vaccine up to 42 days post-vaccination. Id. at 5-6. Haber et al. found “an apparent increase in the number of GBS reports”

²² R. Lahesmaa et al., Molecular Mimicry Between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* Within the Same Region of HLA α_1 -Helix, 86 Clinical Exp. Immunology 399 (1991).

²³ Lawrence B. Schonberger et al., Guillain Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977, 110 Am J. Epidemiology 105 (1979).

²⁴ Penina Haber et al., Vaccines and Guillain-Barré Syndrome, 32 Drug Safety 309 (2009).

to the Vaccine Adverse Event Reporting System (“VAERS”)²⁵ within six weeks following the flu vaccine. Id. at 5. They proposed molecular mimicry as a mechanism for GBS. Id. at 4.

iv. Causation: Althen Prong Two

Regarding a logical sequence of cause and effect, Dr. Napoli first provided a brief factual overview. Pet. Ex. 47 at 4-5. Petitioner received the shingles vaccination and approximately two weeks later she developed right-sided facial symptoms. Id. at 5. Subsequently, on October 29, 2018, she received the flu vaccination, and “within [three] days, . . . developed a left facial droop.” Id. Dr. Napoli opined that this “latter reaction is consistent with bilateral facial diplegia consistent with a variant of [GBS] and explains the onset of her left sided facial symptoms.” Id.

Further, Dr. Napoli noted that Petitioner’s treating physicians, which included specialists, all agreed that Petitioner had a “vaccine induced injury.” Pet. Ex. 47 at 5; see also Pet. Ex. 64 at 2 (citing Pet. Ex. 4 at 20-21 (Dr. Lighthall writing Petitioner has “bilateral complete facial paralysis after the flu and shingles immunizations”); Pet. Ex. 4 at 165-68 (Dr. Kaur assessing the “working diagnosis [was] [GBS] in the setting of recent vaccination (shingles and flu)”); Pet. Ex. 45 at 15-16 (Dr. Saudi writing Petitioner was seen “for follow-up of her bilateral facial paralysis secondary to [GBS]”); Pet. Ex. 45 at 23 (Dr. Lowden suggesting Petitioner not get another vaccination “[if] she had a reaction or GBS after immunization”)).

Dr. Napoli disagreed with Respondent’s expert, Dr. Bigelow, that Petitioner simply had a recurrent episode of Bell’s palsy on the left side. Pet. Ex. 49 at 1. He emphasized that Dr. Lighthall documented that Petitioner’s bilateral facial palsy episodes occurred after vaccination and recommended that she not receive any additional flu or shingles vaccinations. Id. He further noted that while bilateral facial diplegia is rare, it is a variant of GBS. Id.

Dr. Napoli cited articles for the proposition that “facial diplegia” is “an uncommon variant of [GBS]” that has been reported after infections.²⁶ Pet. Ex. 47 at 5. Chan et al.²⁷ reported about a patient with Covid infection who had “acute-onset bilateral facial weakness, dysarthria, and paresthesia in his feet.” Pet. Ex. 56 at 1. Neurological examination revealed “complete facial diplegia and areflexia in the lower extremities.” Id. The patient was diagnosed with GBS and treated with IVIG. Id.

²⁵ “VAERS is a national vaccine safety surveillance program This early warning system is designed to detect possible safety issues with U.S.-licensed vaccines. . . . VAERS data contain information on demographics of the person vaccinated, vaccine type, and [adverse events].” About VAERS, <https://vaers.hhs.gov/about.html> (last visited Mar. 11, 2024).

²⁶ One of the articles cited by Dr. Napoli was authored by Cremieux et al. but only an abstract was provided as the article was in French. See Pet. Ex. 59 at 1. The abstract is not discussed.

²⁷ Jason L. Chan et al., Guillain-Barré Syndrome with Facial Diplegia Related to SARS-CoV-2 Infection, 2020 Canadian J. Neurological Scis. 1.

Susuki et al.²⁸ studied 22 patients with “acute progressive bifacial weakness,” and other clinical signs and symptoms of the more classic forms of GBS, including hyporeflexia or areflexia. Pet. Ex. 55 at 1. They explained that during the course of GBS, “24-60% of GBS patients develop facial nerve paresis,” although almost all of these include bilateral involvement. Id. at 1-2. The authors reported on the preceding symptoms, any positive infectious serology tests results, symptoms, CSF results, NCS, and the presence of relevant antibodies. Id. at 2-4.

After discussing the articles above, Dr. Napoli opined that the fact that Petitioner’s facial palsy after the flu vaccine was only on the left side “does not change the conclusion,” that Petitioner had GBS caused by her flu vaccination. Pet. Ex. 47 at 5. Dr. Napoli concluded that “it is more probable than not that the shingles vaccine²⁹ and [flu] vaccine triggered the patient’s symptoms of facial diplegia consistent with a variant of [GBS].” Id.

Regarding an alternative cause, Dr. Napoli disagreed that Petitioner’s Warthin’s tumor caused her left-sided facial weakness because all of her treating physicians and specialists concluded that her left-sided weakness was caused by GBS. Pet. Ex. 49 at 2. He also noted that Petitioner’s Warthin’s tumor was not becoming larger. Id. Further, Dr. Napoli stated that the Warthin’s tumor would also not explain Petitioner’s right-sided facial weakness or encompass a “complete picture” of Petitioner’s clinical course. Id.

v. **Causation: Althen Prong Three**

Dr. Napoli noted that Petitioner developed right-sided facial paralysis two weeks after receiving the shingles vaccination. Pet. Ex. 47 at 4. Then, in October 2018, she developed left-sided facial paralysis after the flu vaccination. Id. Together these events produced “bilateral facial paralysis.” Id. He opined that because “these events occurred within the setting of [two] separate vaccinations within the timeline of [two] days to [six] weeks is consistent and strongly suggests a temporal association of a vaccine induced injury.” Id.

In support of this opinion, Dr. Napoli cited the paper by Schonberger et al., which “noted an increased risk of GBS following the [flu] vaccination within [five]-week period following vaccination.” Pet. Ex. 47 at 4 (citing Pet. Ex. 58 at 1); see also Pet. Ex. 54 at 1 (showing an increased risk of GBS following swine flu vaccination within six weeks of vaccination but primarily clustered around the second and third weeks post-vaccination).³⁰

²⁸ Keiichiro Susuki et al., A Guillain-Barré Syndrome Variant with Prominent Facial Diplegia, 256 J. Neurology 1899 (2009).

²⁹ The undersigned does not consider Dr. Napoli’s opinions as they relate to the shingles vaccine, as it is a non-covered vaccine.

³⁰ Alexander D. Langmuir et al., An Epidemiological and Clinical Evaluation of Guillain-Barré Syndrome Reported in Association with the Administration of Swine Influenza Vaccines, 119 J. Epidemiology 841 (1984).

b. Respondent's Expert, Dr. Dara G. Jamieson³¹

Dr. Jamieson limited her opinions to the issue of Petitioner's diagnosis and alternative cause of her facial weakness, both on the right and left side. She did not offer opinions as to Althen prong one rebutting Petitioner's theory of causation of GBS based on molecular mimicry. Generally, Dr. Jamieson opined that Petitioner's left-side facial paralysis was caused by her Warthin's tumor and not GBS. Resp. Ex. A at 12.

Dr. Jamieson opined that Petitioner "did not have GBS and [] her third and fourth episodes of unilateral facial weakness did not occur because of either her shingles or [] [flu] vaccines." Resp. Ex. A at 18. She further opined that Petitioner's "first episode of right sided weakness that occurred three and four months after her vaccinations against shingles, and two months prior to her vaccination against [flu], was of unknown cause."³² Id. Dr. Jamieson believed that Petitioner's third episode of left-sided facial weakness was caused by her Warthin's tumor and not GBS. Id.

Dr. Jamieson described the relevant anatomy of the left side of the skull and face, tracing the facial nerve on its course from the skull through the stylomastoid foramen into the deep lobe of the parotid gland. Resp. Ex. A at 12. Petitioner's two prior episodes of left-sided facial weakness were attributed to a "benign tumor in the deep lobe of the left parotid gland in the region of the stylomastoid foramen as the presume etiology." Id. at 12. Dr. Jamieson explained that the cause of facial paralysis in the context of a Warthin's tumor is due to compression or inflammation of the facial nerve by the parotid gland, "especially in the region of the stylomastoid foramen,"³³ which "can cause [] complete facial weakness." Id.

Regarding records that attributed Petitioner's left-sided facial weakness to GBS, Dr. Jamieson opined that these reflected an "erroneous diagnosis," based on "misinform[ation] about the time of Petitioner's vaccinations relative to [Petitioner's] third and fourth episodes of unilateral facial weakness." Resp. Ex. A at 18. According to Dr. Jamieson, Petitioner's "right and then left-sided unilateral facial weakness were separated by approximately two months, with persistent right and new left facial weakness overlapping in time." Id. Thus, Dr. Jamieson

³¹ Respondent filed two expert reports authored by Dr. Jamieson. Resp. Exs. A, C.

³² Dr. Jamieson discussed Bell's palsy, defined as "the spontaneous acute onset of unilateral peripheral facial paresis or palsy in isolation, meaning that no features from the history, neurologic examination, or head and neck examination suggest a specific or alternative causes." Resp. Ex. A, Tab 3 at 1 (Steven G. Reich, Bell's Palsy, 23 Continuum 447 (2017)). If a "specific cause is found . . . it should not be referred to as Bell's palsy." Id. "Bell's palsy may be an autoimmune demyelinating cranial neuritis, and in most cases, it is a mononeuritic variant of [GBS] . . ." Resp. Ex. A, Tab 7 at 1 (A. Greco et al., Bell's Palsy and Autoimmunity, 12 Autoimmunity Revs. 323 (2012)).

³³ Stylomastoid foramen is "a foramen on the inferior part of the temporal bone between the styloid and mastoid processes, for the facial nerve and the stylomastoid artery." Stylomastoid Foramen, Dorland's Med. Dictionary Online, <https://www.dorlandonline.com/dorland/definition?id=77080> (last visited Mar. 11, 2024).

concluded that it is “incorrect” to infer that these “two disparate episodes of unilateral facial weakness” share some “common etiology.” Id.

Further, although Dr. Jamieson acknowledged that Petitioner had absent deep tendon reflexes, this was attributed to Petitioner’s baseline status or it was “baseline mild sensory neuropathy.”³⁴ Resp. Ex. A at 15. Using diagnostic criteria published by van den Berg et al.,³⁵ Dr. Jamieson opined that Petitioner did not have GBS.³⁶ Id. at 15-16 (citing Resp. Ex. A, Tab 12). First, Petitioner did not have limb weakness. Id. at 15. Next, Petitioner did not meet the criteria related to the interval between onset and nadir of weakness of 12 hours to 28 days and subsequent plateau because Petitioner’s episodes of right facial weakness and left facial weakness “were separated by [two] months.” Id. at 16. Third, Petitioner’s EMG did not show “evidence of a chronic demyelinating neuropathy.” Id. Fourth, Petitioner did not have abnormally elevated protein in her cerebrospinal fluid. Id. Lastly, Dr. Jamieson opined that there was an alternative diagnosis for Petitioner’s facial weakness (her Warthin’s tumor). Id.

While Dr. Jamieson agreed that GBS characterized by facial weakness can occur, she opined it is “exceedingly rare,” and occurs “after the onset of extremity symptoms,” not before. Resp. Ex. A at 16. She did not agree that facial weakness (Bell’s palsy) “in isolation” was a “manifestation of GBS.” Id. She opined that “unilateral facial weakness, occurring months before the onset of the recognized motor and sensory deficit” is not GBS, but is idiopathic peripheral facial nerve palsy (Bell’s palsy). Id. at 14, 16.

A review of the medical literature cited by Dr. Jamieson supports her contention that bilateral facial weakness is “exceedingly rare, representing only 0.3-2.0% of facial palsy cases.” Resp. Ex. A, Tab 5 at 1.³⁷ “Unlike unilateral facial palsy, it is often caused by a serious underlying systemic disease . . .” Id. The most common causes are “Lyme disease, [GBS], sarcoidosis, trauma, and [Bell’s palsy].” Id. at 3; see also Resp. Ex. A, Tab 10 at 1 (explaining the underlying etiologic factor in bilateral facial palsy is often an underlying medical condition such as Lyme disease, GBS, or trauma);³⁸ Resp. Ex. A, Tab 15 at 5 (finding asymmetric bilateral

³⁴ Petitioner’s mild sensory neuropathy was not diagnosed until 2021. Pet. Ex. 61 at 11; see also Pet. Ex. 29 at 1-3.

³⁵ Bianca van den Berg et al., Guillain-Barré Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis, 10 Nat. Revs. Neurology 469 (2014).

³⁶ Dr. Jamieson did not offer an opinion about whether Petitioner had a Table claim for GBS using the criteria set forth in the Vaccine Table and its qualifications and aids to interpretation. The Table criteria, however, are very similar to the criteria described in van den Berg et al. See 42 C.F.R. § 100.3(c)(15)(ii); Resp. Ex. A, Tab 12.

³⁷ Alvin Yang & Vikram Dalal, Bilateral Facial Palsy: A Clinical Approach, 13 Cureus e14671 (2021).

³⁸ Robert A. Gaudin et al., Bilateral Facial Paralysis: A 13-Year Experience, 138 Plastic & Reconstructive Surgery 879 (2016).

facial nerve involvement rare, occurring in only 4.9% of GBS cases).³⁹

However, the medical literature Dr. Jamieson cited also stated that cranial neuropathies are common in GBS. Resp. Ex. A, Tab 13 at 3 (“Out of 61 patients, 38 (62.3%) patients had cranial nerve palsies, in that 25 had multiple cranial nerve palsies, and 13 had single isolated nerve palsy [Twenty-eight] had facial nerve palsy, and . . . [three] patients [] had unilateral facial nerve palsy.”).⁴⁰ Sharma et al.⁴¹ also stated that “[c]ranial nerve palsies are frequent in [GBS]. Among cranial nerve palsies, facial nerve palsy is the most common affecting around half of the cases. Facial nerve palsy in [GBS] is usually bilateral,” however, unilateral facial nerve palsies are also reported. Resp. Ex. A, Tab 16 at 1. They described a case study and reports of unilateral facial palsy in children with GBS. *Id.* The child with GBS reported by Sharma et al. was initially diagnosed with unilateral Bell’s palsy, because the bilateral lower limb symptoms were not recognized. *Id.* at 3.

c. Respondent’s Expert, Dr. Douglas C. Bigelow⁴²

Dr. Bigelow opined that Petitioner’s Warthin’s tumor was “the most likely cause of her [left-sided] facial weakness.” Resp. Ex. B at 19. Like Dr. Jamieson, Dr. Bigelow limited his opinions to the issues of Petitioner’s diagnosis and alternative cause of her facial weakness. He did not offer opinions as to Althen prong one rebutting Petitioner’s theory of causation of GBS based on molecular mimicry. Also like Dr. Jamieson, Dr. Bigelow opined that the cause of Petitioner’s right-sided facial weakness was unknown, and therefore, it was idiopathic facial nerve palsy, or Bell’s palsy. *Id.* at 20.

Dr. Bigelow first discussed Petitioner’s right-sided facial weakness that began approximately September 7, 2018. Resp. Ex. B at 17. He noted that relative to her right-sided facial weakness, Petitioner was diagnosed with Bell’s palsy by her primary care physician, Dr. Schwartz. *Id.* About seven weeks later, Petitioner received the flu vaccine, on October 29, 2018. *Id.* Dr. Bigelow observed that because the flu vaccine was given seven weeks after the onset of Petitioner’s right-sided facial palsy, there was no relationship between the two events. *Id.*

Regarding Petitioner’s left-sided facial weakness, Dr. Bigelow opined that onset was about November 3, 2018, approximately five days after receiving the flu vaccination. Resp. Ex. B at 17. Dr. Bigelow noted that Petitioner had two prior episodes of left-sided facial weakness. *Id.* at 18. Based on a history documented by Dr. Lighthall, Petitioner had prior left-sided facial weakness about ten years and four years prior to this third episode. *Id.* Although Dr. Lighthall’s

³⁹ Xuanyu Huang et al., Case Report and Literature Analysis: Guillain-Barré Syndrome with Delayed Unilateral Facial Palsy, 12 Frontiers Neurology 658266 (2021).

⁴⁰ Amita Bhargava et al., A Study of Guillain-Barré Syndrome with Reference to Cranial Neuropathy and Its Prognostic Implication, 5 J. Neurosciences Rural Prac. S43 (2014).

⁴¹ Kamal Sharma et al., Guillain-Barré Syndrome with Unilateral Peripheral Facial and Bulbar Palsy in a Child: A Case Report, 7 SAGE Open Med. Reps. (2019).

⁴² Respondent filed two expert reports authored Dr. Bigelow. Resp. Exs. B, D.

history indicated that Petitioner's prior episodes resolved spontaneously, Dr. Bigelow noted that Petitioner had a "slight lid lag" when closing the left eye as observed by Dr. Goldberg on October 2, 2017. Id. (citing Pet. Ex. 3 at 145; Pet. Ex. 13 at 103). However, other records documented that Petitioner's left facial nerve was intact and normal. Id.

After recounting Petitioner's history of prior left-side facial weakness, Dr. Bigelow discussed Petitioner's Warthin's tumor. He explained that Warthin's tumors are benign solid tumors that contain "multiple cysts with papillary projections." Resp. Ex. B at 18. The cystic portions can sometimes enlarge, "leading to rupture of the cysts and inflammation." Id. He explained that "it is very uncommon" for a Warthin's tumor to cause facial weakness, but "it does occur." Id. Dr. Bigelow noted that Dr. Goldberg suggested that Petitioner's prior episodes of left-sided facial weakness may have been caused by her Warthin's tumor. Id. (citing Pet. Ex. 3 at 145; Pet. Ex. 13 at 103).

In support of his opinions, Dr. Bigelow cited Cobb et al.,⁴³ which described a patient with a Warthin's tumor who had pain and facial nerve dysfunction, and where fine needle aspiration of the tumor revealed "acute, chronic, and granulomatous inflammation and rare squamous cells in a background of finely granular necrotic debris." Resp. Ex. B at 18 (citing Resp. Ex. B, Tab 6 at 4). Dr. Bigelow opined that there were "strong similarities" between the case reported by Cobb et al. and Petitioner's experience, including cytology results showing inflammation and necrosis, and the clinical history, in that both had significant pain. Id. at 19.

Using measurements of Petitioner's Warthin's tumor reported from her CT scans from 2016 to 2018, as well as his own review of some of the scans, Dr. Bigelow suggested that Petitioner's tumor had increased in size over that two-year period. Resp. Ex. B at 19. He opined that it was "possible the mild enlargement of [Petitioner's] tumor contributed to her episodes of recurrent left-sided weakness." Id.

However, there are distinct differences between the clinical course of Petitioner and that experienced by the patient reported by Cobb et al. The patient in Cobb et al. was noted to have pain and facial nerve dysfunction "following [an] abrupt increase" in the size of the tumor. Resp. Ex. B, Tab 6 at 4. Fine needle aspiration "yielded murky, brown, viscous fluid," and "the residual mass was also aspirated." Id. Histologic examination showed "extensive necrotizing granulomatous inflammation, with acute and chronic inflammation, fibrosis[,] and squamous metaplasia." Id. The authors concluded that there was a "spontaneous infarction"⁴⁴ of the Warthin's tumor caused by a "mycobacterial or fungal infection." Id. The authors also stated that nerve dysfunction was "very rarely" caused by Warthin's tumors. Id. They noted, "[t]his report is probably the first account in which these [two] conditions [facial nerve paralysis and

⁴³ Camilla J. Cobb et al., Fine Needle Aspiration Cytology and Diagnostic Pitfalls in Warthin's Tumor with Necrotizing Granulomatous Inflammation and Facial Nerve Paralysis, 53 Acad. Cytology 431 (2009).

⁴⁴ An infarction is "an area of coagulation necrosis in a tissue due to local ischemia resulting from obstruction of circulation to the area." Infarct, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=25169> (last visited Mar. 11, 2024).

necrosis with spontaneous infarction] are observed in a single [Warthin's tumor]." Id.

Using the Cobb et al. report as support, Dr. Bigelow opined that Petitioner "most likely ha[d] a rupture of a Warthin's tumor cyst adjacent to her facial nerve causing inflammation, necrosis, and the abrupt onset of severe pain along with the acute facial weakness." Resp. Ex. B at 20. He observed that Petitioner's pain improved after several days, and her aspiration showed "acute inflammation with necrosis suggestive of an associated inflammatory process." Id. (citing Pet. Ex. 8 at 58). Dr. Bigelow likened this pathology to the Cobb et al. case report. Id. He also explained that necrosis of the tumor would cause it to decrease in size, which he argued is seen in Petitioner's subsequent CT scan performed in 2020. Id.; see Pet. Ex. 45 at 1-3. Dr. Bigelow further asserted that GBS would not cause the pain that Petitioner experienced or cause her tumor to decrease in size. Resp. Ex. B at 20.

Dr. Bigelow cited several case reports describing facial nerve palsy in the setting of rapid growth of Warthin's tumors where aspiration revealed abnormal fluid, indicating marked necrosis or hemorrhage. Resp. Ex. B at 18-20 (citing Resp. Ex. B, Tab 8 (describing hemorrhaging as a cause of swelling and compression of the facial nerve)).⁴⁵

For example, O'Dwyer et al.⁴⁶ described a patient with left facial weakness and a 14-year history of a left parotid gland mass. Resp. Ex. B, Tab 2 at 1. Over the course of a year's time, the tumor had grown rapidly into a 5.0 x 6.0 cm mass, and was feared to be malignant, and so removal by surgery was recommended. Id. at 4. Upon removal, the mass measured 9.0 x 6.5 x 3.0 cm, and contained "small cystic spaces" that contained "slightly turbid, brownish colored fluid." Id. Histology was consistent with a Warthin's tumor that had undergone marked degeneration and within the fibrous tissue, branches of the facial nerve were found that had also undergone degeneration. Id. The authors suggested that "long-standing inflammatory process gave rise to fibrosis and scarring . . . with entrapment of branches of the facial nerve." Id. at 7.

Maini and Osborne⁴⁷ described a case report of "massive necrosis of Warthin's tumor with associated facial palsy and subsequent clinical and radiological disappearance of the tumor." Resp. Ex. B, Tab 3 at 1. The patient also had "swelling over the right parotid region of [six] months duration." Id. The patient's tumor, which measured 3.5 x 2.5 x 3.8 cm, "underwent a rapid increase in size and ruptured exuding khaki colored viscous fluid." Id. at 1-2.

⁴⁵ M.G. Berry et al., Acute Facial-Nerve Paralysis with Parotid Adenolymphoma, 54 Brit. J. Plastic Surgery 454 (2001).

⁴⁶ Timothy P. O'Dwyer et al., A Pseudo-Malignant Warthin's Tumor Presenting with Facial Nerve Paralysis, 19 J. Otolaryngology 353 (1990).

⁴⁷ Sangeeta Maini & J.E. Osborne, Ischaemic Necrosis and Facial Palsy in Warthin's Tumour of the Parotid Gland, 29 Auris Nasus Larynx 99 (2002).

Marioni et al.⁴⁸ described a patient with a painful parotid swelling with a mass of 6.0 x 3.0 cm. Resp. Ex. B, Tab 7 at 1. Aspiration of the mass withdrew purulent exudate. Id. The tumor grew and caused facial palsy. Id. at 1-2; see also Resp. Ex. B, Tab 5 (describing a patient whose 5.0 cm right parotid mass caused facial palsy).⁴⁹

Another case cited by Dr. Bigelow described rapid swelling of a tumor, which also produced “brown, cloudy material” when aspirated and although cancer was suspected, the tumor was benign. Resp. Ex. B, Tab 4 at 1.⁵⁰ The rapidly progressive tumor measured 6.0 x 4.0 x 3.0 cm. Id. The patient had swelling on the left side with incomplete facial palsy. Id.

These cases show that facial palsy can occur as a result of Warthin’s tumor. But as compared with the case reports, Petitioner’s tumor was smaller, measuring approximately 1.7 x 1.8 x 2.1 cm. Resp. Ex. B at 19 (citing Pet. Ex. 3 at 16-17, 53-54, 228-29; Pet. Ex. 7 at 49-50; Pet. Ex. 45 at 13-14).⁵¹ Her fine needle aspiration did not produce the turbid brown colored fluid, and she was followed by specialists, who performed assessments that did not show rapid or significant growth of her Warthin’s tumor.

Next, Dr. Bigelow explained that recurrent episodes of facial palsy and “bilateral simultaneous facial weakness” are “extremely uncommon.” Resp. Ex. B at 20. He identified many causes for both conditions. Id. Regarding bilateral facial palsy, Dr. Bigelow further described the two types, synchronous or asynchronous. Id. In synchronous bilateral facial palsy, “involvement of the contralateral side occurs within 30 days.” Id. In the asynchronous type, “involvement of the contralateral side occurs after 30 days.” Id. He stated that the “differential diagnosis of the two types is different.” Id. GBS is one of the causes of the synchronous forms of facial nerve palsy. Id. However, Dr. Bigelow did not opine that GBS was a known cause of asynchronous facial nerve palsy. One of the causes of the asynchronous form is Bell’s palsy. Id. Another suggested cause, described as controversial, for “recurrent facial nerve paralysis” is “reactivation of Herpes Simplex Virus [] in the geniculate ganglion.” Resp. Ex. B, Tab 9 at 6. The mechanism of facial paralysis was thought to be caused by “repeated episodes of degeneration and rupture of the characteristic cystic spaces with resulting leakage of the contents.” Id.

⁴⁸ Gino Marioni et al., Facial Nerve Paralysis Secondary to Warthin’s Tumour of the Parotid Gland, 117 J. Laryngology & Otology 511 (2003).

⁴⁹ Raymond W. Lesser & J. Gershon Spector, Facial Nerve Palsy Associated with Warthin’s Tumor, 111 Archives Otolaryngology Head & Neck Surgery 548 (1985).

⁵⁰ Chiaki Koide et al., Pathological Findings of the Facial Nerve in a Case of Facial Nerve Palsy Associated with Benign Parotid Tumor, 120 Archives Otolaryngology Head & Neck Surgery 410 (1994).

⁵¹ CT done September 8, 2016 showed Petitioner’s tumor measured 1.8 x 1.8 cm. Pet. Ex. 3 at 53-54. CT done October 2, 2017 showed Petitioner’s tumor measured 1.7 x 1.8 x 2.1 cm. Id. at 16-17. And CT done October 18, 2018 showed Petitioner’s tumor measured 1.8 x 1.74 x 2.2 cm. Id. at 228-29.

According to Dr. Bigelow, Petitioner's right-sided facial weakness began about seven weeks before she received the flu vaccine, and therefore, it could not have caused her GBS.⁵² Resp. Ex. B at 21. Therefore, he argued GBS does not explain Petitioner's bilateral facial palsy. Id. Dr. Bigelow also noted that Petitioner's expert does not acknowledge the Warthin's tumor, and its proximity to the facial nerve, or the note by Dr. Goldberg suggesting the possible involvement of the Warthin's tumor. Id. (citing Pet. Ex. 3 at 145; Pet. Ex. 13 at 103).

Further, Dr. Bigelow asserted that when GBS causes bilateral facial palsy, the onset is synchronous. Resp. Ex. B at 21. He noted that Petitioner's right-sided weakness began on September 7, 2018, while her left-sided palsy started around November 3, 2018, approximately 55 days later. Id. Dr. Bigelow opined that this time frame is "well outside the time frame of 30 days" and therefore, it is not synchronous. Id. In support of this opinion, Dr. Bigelow cited Wakerley and Yuki.⁵³ Id. (citing Resp. Ex. B, Tab 12).

Wakerley and Yuki described the unusual subtype of GBS called bifacial weakness with paresthesias ("BFP"), characterized by "acute-onset bifacial weakness" that occurs in the absence of limb weakness. Resp. Ex. B, Tab 12 at 1. This subtype is associated with "hyporeflexia or areflexia." Id. at 2. The largest case series studied 22 patients with facial palsy caused by GBS. Id. at 1-2. "In a third of patients, facial weakness appeared on both sides on the same day. Often, however, development with was sequential over a few days and was usually more pronounced on the side first affected." Id. at 2. "Mild bulbar symptoms, limb weakness, or ataxia were only noted in a minority of patients. Deep tendon reflexes were absent . . . in 45% of patients In all patients, neurological signs progressed acutely over [four] weeks before reaching a plateau or beginning to improve." Id.

Dr. Bigelow opined that Petitioner's clinical course was not like that described by Wakerley and Yuki, because of the time span of 55 days between the onset of her left-sided palsy. Resp. Ex. B at 21-22. He also noted that Petitioner's course did not progress over a period of four weeks "before reaching a plateau or beginning to improve." Id. (quoting Resp. Ex. B, Tab 12 at 2).

In summary, Dr. Bigelow disagreed that Petitioner suffered from GBS and instead opined that Petitioner had right-sided facial weakness of unknown cause, and that her left-sided facial weakness was "related to her Warthin's tumor." Resp. Ex. B at 22; see also Resp. Ex. D at 3. He disagreed that the vaccinations she received played a causal role in either her right- or left-sided facial weakness. Resp. Ex. B at 22; Resp. Ex. D at 3.

⁵² Dr. Bigelow discussed his opinions about Petitioner's MRI, which "demonstrated enhancement of the facial nerve of the right side . . . which is a typical finding in Bell's palsy, but not with GBS." Resp. Ex. D at 2. However, enhancement of the facial nerve was not described by the radiologist who interpreted the study. See Pet. Ex. 7 at 49-50; Pet. Ex. 5 at 15.

⁵³ Benjamin R. Wakerley & Nobuhiro Yuki, Isolated Facial Diplegia in Guillain-Barre Syndrome: Bifacial Weakness with Paresthesias, 52 Muscle Nerve 927 (2015).

III. LEGAL FRAMEWORK

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” Rooks v. Sec’y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner’s burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

“Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case.” Flores v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner’s evidence on a requisite element of the [P]etitioner’s case-in-chief.”); Pafford, 451 F.3d at 1358-59 (“[T]he presence of multiple potential causative agents makes it difficult to attribute ‘but for’ causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.”).

B. Factual Issues

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records, specifically contemporaneous medical records, are presumed to be accurate and generally “warrant consideration as trustworthy evidence.” Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that “medical records are accurate and complete as to all the patient’s physical conditions”); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” (quoting Murphy v. Sec’y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff’d per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den’d after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they “contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” Id. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is “consistent, clear, cogent, and compelling.” Sanchez v. Sec’y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec’y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. den’d, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App’x 843 (Fed. Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec’y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Lowrie v. Sec’y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl.

Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Petitioner claims she suffered a GBS Table injury and claims in the alternative, that her injury was caused-in-fact by a vaccination. To prove the latter, Petitioner must establish, by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen, 35 F.3d at 548-49. Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in Petitioner’s favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”); Althen, 418 F.3d at 1280 (noting that “close calls” are resolved in Petitioner’s favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec’y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance.

Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. ANALYSIS

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since “each prong of the Althen test is decided relative to the injury[.]” determining facts relating to the claimed injury can be significant. Id.

Based on the joint submission, the parties agree that Petitioner’s relevant injury is “left-sided facial paralysis.” Joint Submission at 1. Petitioner, however, asserts her facial paralysis was caused by GBS, while Respondent contends it was caused by her Warthin’s tumor. See id. at 1-2.

After a review of the entire record, including the medical records, expert reports, and the parties’ briefs, in accordance with the applicable legal standards, the undersigned finds GBS to be Petitioner’s appropriate diagnosis. This finding is based on the following reasons.

First, Petitioner’s treating specialists, otolaryngologist Dr. Lighthall⁵⁴ and neurologist Dr. Sun, both diagnosed her with GBS. On November 5, 2018, Petitioner was seen by Dr. Lighthall, who noted that Petitioner’s voice was hoarse and that she had bilateral facial weakness after vaccination. Dr. Lighthall was concerned that Petitioner had GBS. The next day, November 6, Dr. Sun noted that Petitioner had had imbalance for three days, that she had difficulty with swallowing, bilateral facial numbness, and abnormal reflexes (Biceps 1+, Brachioradialis 2+, Triceps 1+, Patellar 0, and Achilles 0). Pet. Ex. 4 at 174. Dr. Sun agreed that the differential diagnosis included GBS. By the next day, November 7, Petitioner was areflexic. Dr. Sun documented Biceps 0, Brachioradialis 0, Triceps 0, Patellar 0, and Achilles 0. Id. at 170. This examination shows that there was a change in Petitioner’s reflexes from one day to the next, with Petitioner becoming areflexic by November 7. Dr. Sun ordered IVIG treatment, appropriate for GBS.

The diagnosis of GBS did not change after the November 14, 2018 biopsy for the Warthin’s tumor. On December 3, 2018, Dr. Lighthall again wrote that Petitioner’s “presumptive diagnosis” was GBS, although she acknowledged that the “picture [was] muddled somewhat due to left deep lobe parotid tumor.” Pet. Ex. 8 at 10. Thus, Dr. Lighthall acknowledged Petitioner’s Warthin’s tumor, and the difficulty in reaching a diagnosis, but she opined that Petitioner still had a presumptive diagnosis of GBS. And Dr. Lighthall restated the diagnosis of GBS when she saw Petitioner throughout 2019.

Respondent’s expert, Dr. Jamieson acknowledged Petitioner’s absent deep tendon

⁵⁴ Dr. Lighthall had a Multidisciplinary Facial Nerve Surgery Clinic at Penn State Hershey Medical Center. See Pet. Ex. 4 at 41.

reflexes, but she attributed the abnormality to Petitioner's baseline, or the mild sensory neuropathy diagnosed in 2021. However, Dr. Sun performed several assessments of Petitioner's reflexes, and these assessments showed a progressive decline in reflexes over the course of several days. These serial assessments and the change from having decreased reflexes to no reflexes is a clinical finding that weighs against Dr. Jamieson's argument that absent reflexes were a baseline for Petitioner or that they were caused by some later diagnosed neuropathy.

Respondent's experts, Dr. Jamieson and Dr. Bigelow, argued that instead of GBS, Petitioner's left-sided facial palsy was caused by her Warthin's tumor. Dr. Jamieson asserted that the tumor caused compression of the nerve, especially the part of the nerve in the region of the stylomastoid foramen. Dr. Bigelow offered a theory based on a scenario that the tumor enlarged and ruptured adjacent to Petitioner's nerve, causing inflammation, necrosis, and the abrupt onset of pain.

The theories offered by Dr. Jamieson and Dr. Bigelow, however, do not account for Petitioner's clinical course, specifically that she was noted to have an imbalance for three days, a hoarse voice, difficulty swallowing, and especially the fact that she experienced decreased and then absent deep tendon reflexes. These clinical findings described by the treating physicians support the diagnosis of GBS with cranial neuropathy involvement.

Dr. Lighthall and Dr. Sun also documented signs and symptoms that may be seen with bulbar palsy, specifically the finding that Petitioner was hoarse and had difficulty swallowing. Sharma et al. explained that bulbar palsy "implies the involvement of lower cranial nerves IX, X, XI, and XII." Resp. Ex. A, Tab 16 at 3. "Patients with signs of bulbar involvement such as difficulty swallowing, dysphonia, and/or shoulder weakness need close monitoring," as they can develop respiratory paralysis. *Id.* The experts did not address these abnormalities. However, the documentation of these abnormalities by the specialists indicate that they evaluated Petitioner for cranial neuropathy associated with GBS.

There are several problems with Dr. Bigelow's opinion that "it was possible the mild enlargement of [Petitioner's] tumor contributed to her episodes of recurrent left-sided facial weakness." Resp. Ex. B at 19. First, Dr. Bigelow states this opinion as a "possibility." Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See *Waterman*, 123 Fed. Cl. at 573-74; *Moberly*, 592 F.3d at 1322; *Boatmon*, 941 F.3d at 1359-60; *de Bazan*, 539 F.3d at 1351.

The second problem with Dr. Bigelow's opinion that Petitioner's Warthin's tumor may have become enlarged or ruptured and caused her facial paralysis is that it is based on case reports where the facts are different. The case reports by Cobb et al. and others show that facial palsy can occur as a result of Warthin's tumor. But as compared with the case reports, Petitioner's tumor was different—her fine needle aspiration did not produce turbid brown colored fluid, and she was followed by specialists who did not opine that Petitioner had rapid or significant growth of her Warthin's tumor.⁵⁵ CT done October 2, 2017 showed that Petitioner's

⁵⁵ A review of the records shows that Dr. Goldberg and Dr. Lighthall monitored the size of Petitioner's tumor, particularly since rapid growth can indicate malignancy.

tumor measured 1.7 x 1.8 x 2.1 cm. Pet. Ex. 3 at 16-17. On October 18, 2018,⁵⁶ her CT showed it measured 1.8 x 1.74 x 2.2 cm and was described as “stable.” Pet. Ex. 3 at 228-29. Dr. Lighthall wrote that it was “unchanged in size.” Pet. Ex. 4 at 41. CT done January 16, 2020 showed the tumor measured 1.5 x 1.5 cm. Pet. Ex. 45 at 13-14. Dr. Goldberg opined that it showed “no areas of concern for growth.” Pet. Ex. 43 at 90. Based on these serial CT scans, there was no appreciable growth in Petitioner’s Warthin tumor in 2018. While there was a decrease in 2020, Dr. Goldberg did not express any concern.

Another argument against GBS offered by Dr. Jamieson and Dr. Bigelow is the fact that Petitioner’s bifacial weakness was not synchronous. Dr. Bigelow opined that Petitioner’s right-sided weakness began September 7, 2018,⁵⁷ and that her left-sided facial palsy began about 55 days later on November 3, 2018. Dr. Bigelow is correct to conclude that Petitioner’s right-side facial paralysis occurred approximately seven weeks before her left-sided weakness. Based on literature filed in this case, asynchronous forms with involvement of the opposite side usually occur within 30 days. Petitioner’s left-sided facial paralysis exceeded that timeframe.

Dr. Jamieson asserted that the physicians were not aware of the accurate chronology of events when they made statements associating the right- and left-sided facial palsy or when they attributed the bifacial weakness to GBS. However, Dr. Jamieson’s assertion is not supported by the records. On October 26, 2018, Petitioner saw Dr. Lighthall and reported that she developed right-sided facial paralysis in September, about two weeks after receiving the shingles vaccination.⁵⁸ Dr. Lighthall documented this history. Further, she evaluated Petitioner after the onset of her right-sided facial weakness, and prior to Petitioner’s left-sided facial paralysis. On November 5, 2018, Dr. Lighthall saw Petitioner again. This time Petitioner had bilateral facial paralysis. Again, Dr. Lighthall took and documented a history. Given that she saw Petitioner twice in a matter of weeks, and that her records reflect the history of these events, it cannot be assumed that Dr. Lighthall was unaware of the correct time intervals between Petitioner’s right-sided and left-sided facial weakness.

Regardless, the undersigned is not tasked with resolving the etiology of Petitioner’s right-sided facial palsy. The undersigned, therefore, makes no finding as to the diagnosis or cause of Petitioner’s right-sided facial palsy. The only relevant questions are the diagnosis and cause of Petitioner’s left-sided facial weakness.

For all of the reasons discussed above, the undersigned finds that Petitioner has proven

⁵⁶ An MRI performed November 5, 2018 showed different measurements, 2.6 x 2.6 x 2.3 cm in size. Pet. Ex. 7 at 49-50. It is not clear why the MRI measurements differed from those obtained by CT and Dr. Bigelow did not address that fact.

⁵⁷ History taken by Dr. Sun on November 6, 2018 stated that right-sided facial palsy began on September 10, 2018. Pet. Ex. 4 at 103.

⁵⁸ Petitioner received two doses of the shingles vaccinations, the first on April 30, 2018 and the second on August 7, 2018. About two weeks later would have been August 21, 2018. Petitioner saw Dr. Schwartz on September 10, 2018, at which time she reported that her right-side facial weakness was gradual over the past few days, placing onset approximately September 7.

by preponderant evidence that her diagnosis was GBS and that her left-sided facial palsy was caused by GBS.

B. Table Claim

While the undersigned finds Petitioner's diagnosis was GBS, Petitioner does not meet the Table definition for GBS for a Table claim. Under the Vaccine Table Qualifications and Aids to Interpretation, the following five criteria must be met for diagnosis of GBS:

- (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
- (B) A monophasic illness pattern;
- (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
- (E) The absence of an identified more likely alternative diagnosis.

42 C.F.R. § 100.3(c)(15)(ii). Supportive, but not required, evidence of a GBS diagnosis “includes electrophysiologic findings consistent with GBS or an elevation of [CSF] protein with a total CSF white blood cell count below 50 cells per microliter.” *Id.* at § 100.3(c)(15)(iv).

A review of the medical records shows that Petitioner does not meet the Table criteria because she did not have limb weakness. Dr. Napoli acknowledged this in his expert report, when he noted that Petitioner did not have “extremity weakness.” Pet. Ex. 47 at 5. Because Petitioner does not meet this criterion, she has failed to prove by preponderant evidence that she meets the Table definition of GBS.⁵⁹

C. Causation-in-Fact

Because Petitioner does not meet the Table criteria for GBS, the undersigned next addresses the question of whether she has proven her causation-in-fact claim for GBS.

1. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a “sound and reliable” medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”). If

⁵⁹ The Vaccine Injury Table also include other subtypes of GBS, but Petitioner does not meet the criteria for these other types of GBS, including the Miller Fisher Syndrome subtype of GBS.

Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 (“The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); Perreira v. Sec’y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an “expert opinion is no better than the soundness of the reasons supporting it” (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

As for Althen prong one, the undersigned finds that Petitioner has provided preponderant evidence that the flu vaccine can cause GBS and that molecular mimicry is a sound and reliable causal theory. There are several reasons for this finding. First, GBS is a Table injury following flu vaccination. See 42 C.F.R. § 100.3(a). When proposing the addition of GBS to the Table, Respondent discussed the mechanism by which this injury is caused, specifically stating, “[i]t is not fully understood why some people develop GBS, but it is believed that stimulation of the body’s immune system, as occurs with infections, can lead to the formation of autoimmune antibodies and cell-mediated immunity that play a role in its development.” National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45145 (July 29, 2015).

The undersigned takes judicial notice of the fact that Respondent added GBS after receipt of a flu vaccine to the Table. Such recognition of the causal association between vaccine and injury has been held to support the establishment of the theory required by the first Althen prong. See Doe 21 v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 178, 199 (2009), rev’d on other grounds, 527 F. App’x 875 (Fed. Cir. 2013). The undersigned also notes that prior decisions found petitioners had met Althen prong one even before GBS was added to the Table. See, e.g., Stitt v. Sec’y of Health & Hum. Servs., No. 09-653V, 2013 WL 3356791, at *8-10 (Fed. Cl. Spec. Mstr. May 31, 2013); Stewart v. Sec’y of Health & Hum. Servs., No. 06-777V, 2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011); Barone v. Sec’y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *8-9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014).

Second, Respondent has conceded entitlement to compensation in many cases where petitioners have had GBS following the flu vaccination. See, e.g., Morgan v. Sec’y of Health & Hum. Servs., No. 19-1105V, 2020 WL 4725625 (Fed. Cl. Spec. Mstr. June 15, 2020); Robinson v. Sec’y of Health & Hum. Servs., No. 18-0088V, 2019 WL 2383530 (Fed. Cl. Spec. Mstr. Apr. 2, 2019); Martinez v. Sec’y of Health & Hum. Servs., No. 20-0709V, 2020 WL 7054282 (Fed. Cl. Spec. Mstr. Oct. 27, 2020). Even after GBS was added to the Table, Respondent conceded or did not contest cases which may not have met the Table criteria. See, e.g., Johnson v. Sec’y of Health & Hum. Servs., No. 16-1356V, 2017 WL 7513282 (Fed. Cl. Spec. Mstr. Sept. 22, 2017); Hinton v. Sec’y of Health & Hum. Servs., No. 16-1140V, 2018 WL 4391071 (Fed. Cl. Spec. Mstr. May 29, 2018), mot. for rev. den’d, 2023 WL 3815047 (Fed. Cl. May 15, 2023).

Third, Petitioner’s expert, Dr. Napoli offered an opinion based on the theory of molecular mimicry as it relates to GBS. See Pet. Ex. 47 at 4. In support of this theory, Dr. Napoli also filed well known medical literature filed that supports molecular mimicry as a sound and reliable theory. See, e.g., Pet. Ex. 53 at 4 (proposing molecular mimicry as a mechanism for GBS); Pet.

Ex. 51 at 1 (describing the role of molecular mimicry in inflammatory diseases); Pet. Ex. 58 at 18 (suggesting an immune etiology such as molecular mimicry for GBS).

Further, the paper by Sharma et al. stated that facial palsies in GBS “can be caused by antibody-mediated demyelination,” consistent with molecular mimicry. Resp. Ex. A, Tab 16 at 3. Thus, the fact that Petitioner had a subtype of GBS does not change the mechanistic theory of molecular mimicry.

Lastly, Respondent’s experts did not refute Dr. Napoli’s causation opinions based on molecular mimicry.

For all of these reasons, undersigned finds that Petitioner has provided preponderant evidence of a sound and reliable causal theory, satisfying Althen prong one.

2. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the “diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”).

Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

The undersigned finds that Petitioner has provided preponderant evidence of a logical sequence of cause-and-effect, as required by Althen prong two. Here, Petitioner’s clinical course as described in the medical records, and specifically the records of Dr. Sun and Dr. Lighthall, show a time course consistent with the mechanism and the timeframe within which GBS can occur following vaccination.

To summarize, Petitioner received her flu vaccination on October 29, 2018 and she presented to the ED on November 2, 2018 with headache and pain in her forehead and left-sided cheek and was diagnosed with left trigeminal neuralgia. She returned to the ED the next day, November 3, with left-sided facial weakness. On November 5, Dr. Lighthall documented hoarse voice and facial paralysis. On November 6, Dr. Sun documented that Petitioner had imbalance for three days, numbness of her face bilaterally, difficulty swallowing,⁶⁰ and decreased reflexes. Petitioner had no reflexes the following day, and IVIG was ordered. Petitioner had improvement with treatment and was discharged on November 12, 2018. The undersigned finds this clinical course to be consistent with GBS characterized by cranial nerve involvement as described in the medical literature filed by the parties. Further, as described above, both of Petitioner's treating physicians diagnosed her with GBS.

Moreover, Petitioner was worked up for alternative etiologies and none were found. Petitioner reported no recent history of infections prior to the onset of her GBS. Pet. Ex. 4 at 103. Blood work for Lyme disease, HIV, and syphilis was negative. *Id.* at 89. CSF revealed normal white blood cell count and upper normal limits of glucose and protein but no indication of infection. *Id.* at 89, 172. And as discussed above, the undersigned finds that Petitioner's Warthin's tumor was not the cause of her left-sided facial palsy.

For the above reasons, the undersigned finds that Petitioner has proven by preponderant evidence a logical sequence of cause-and-effect, satisfying Althen prong two.

3. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). *Id.*; see also Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542. Thus, prong three contains two parts. First, Petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, they must demonstrate that the onset of the disease occurred in this period. Shapiro, 101 Fed. Cl. at 542-43.

For a Table claim of GBS following the flu vaccine, onset must fall within three and 42 days of vaccination. 42 C.F.R. § 100.3(a). For non-Table claims, or causation-in-fact claims, special masters have generally found that petitioners are entitled to causation where onset occurs up to two months, eight weeks or 56 days, following the flu vaccination. Barone v. Sec'y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) ("[S]pecial masters have never gone beyond a two-month (meaning eight week) interval in holding that a vaccination caused a demyelinating illness.").

⁶⁰ Dysphagia was also documented on November 5, 2018 on the MRI form. Pet. Ex. 4 at 21.

Petitioner received her flu vaccine on October 29, 2018. The undersigned finds that onset of Petitioner's GBS occurred on or about November 2, 2018, when she presented with left-sided facial pain. Therefore, onset was about four days after vaccination. Petitioner's onset occurred within the three-to-42-day window in the Vaccine Injury Table, which is also consistent with the mechanism of molecular mimicry for demyelinating conditions such as GBS.

Therefore, the undersigned finds that Petitioner has proven Althen prong three by preponderant evidence.

D. Alternative Causation

Because the undersigned concludes that Petitioner has established a prima facie case, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence "that [Petitioner's] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther, 485 F.3d at 1151. In order to meet his burden, Respondent must demonstrate by preponderant evidence "that a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor)." de Bazan, 539 F.3d at 1354 (emphasis omitted). The Vaccine Act provides that "factors unrelated to the administration of the vaccine," are those "which are shown to have been the agent . . . principally responsible for causing the petitioner's illness, disability, injury, condition or death." § 13(a)(2)(B).

Here, Respondent identified an alternative cause of Petitioner's illness—her Warthin's tumor. While Respondent presented evidence to support the position, as discussed above in the analysis related to diagnosis, the undersigned found that Petitioner's accurate diagnosis was GBS. And Respondent failed to establish preponderant evidence to show that Petitioner's GBS was caused by a source other than her flu vaccination—here, her Warthin's tumor.

Thus, Respondent did not prove by a preponderance of evidence that Petitioner's injury was "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

V. CONCLUSION

For the reasons discussed above, the undersigned finds that Petitioner has established by preponderant evidence that she is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master